

Service d'immuno-oncologie ÉTUDES CLINIQUES v. DECEMBRE 2021

thoracique

CONTACTS

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Indication	Study name	Treatment	Stage & histological type	Line	Other key eligibility criteria
THOR	Amgen 20160323 Phase I	Part A: AMG757 Part C: AMG757 + pembrolizumab	RR SCLC	who progressed or recurred after at least 1 platinum based regimen	 Histologically confirmed SCLC If combined diagnosis of small cell carcinoma with predominant small cell, may be considered for inclusion after discussion with medical monitor ECOG 0-2 At least 2 measurable lesions per mRecist1.1 within 21d prior to first dose of AMG757. If 1 lesion only, can be discussed with medical monitor Subject with brain mets are eligible if definitive therapy was completed 2weeks prior 1st dose of AMG757; and no evidence au CNS progression. Patients on chronic anticoagulation therapy who do not meet PT/INR and PTT or aPTT ≤1.5 ULN may be eligible after discussion with medical monitor Baseline O2 sat >90% on room air, no pleural effusion Cardiac ejection fraction ≥ 50%, no evidence or pericardial effusion (by Echo or Muga) and no clinically significant ECG findings
THOR	Phosplatin Therapeutics PAVE PT112-103 Phase I/II	Avelumab + PT112 (Dose confirmation cohort)	Metastatic or locally advanced NSCLC progressing on PD-1/PDL-1 therapy	-Received no more than three prior regimens, with PD-1 / PD-L1-containing therapy administered as their most recent therapy - failed to achieve a PR or CR. — or if not progressing, period of SD must be a minimum of four (4) months	 measurable disease by irRECIST criteria Availability of tumor material (<3months) or tumor biopsy ECOG: 0 or 1 Exc: Known symptomatic central nervous system (CNS) metastases Exc: Persisting toxicity related to prior therapy is Grade >1 Exc: Diagnosis of any other malignancy within 2 years Exc: Clinically significant or active cardiovascular disease Exc: Known alcohol or drug abuse Exc: Known allergic reaction to methotrexate
THOR	BMS CA022-001 Phase I	Part IB (Nivolumab 480mg + BMS 986218) Part2B monotherapy BMS 986218 (7, 20 ou 70mg)	Adanced or metastatic	Part 1B: Progressed or relapse after at least 2 standard systemic with proven survival benefit according to their tumor type in advanced or metastatic disease Part 2B: NSCLC prior anti PD-1 /anti PD-L1	 ECOG PS: 0-1 if anti-PD-1 therapy is approved in a given indication, participants are eligible to receive this treatment as part of the combination regimen in this study prior to having completed 2 prior systemic therapy regimens after discussion and agreement with the Medical Monitor (or designee) Toxicity (except for alopecia) related to prior anti-cancer therapy and/or surgery, unless the toxicity is either resolved, returned to baseline or Grade 1, or deemed irreversible. No Prior participation in an anti-CTLA-4-NF clinical study or therapy Participants with primary CNS malignancies, or tumors with CNS metastases as the only site of disease, will be excluded



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Indication	Study name	Treatment	Stage & histological type	Line	Other key eligibility criteria
THOR	CHUV-DO-0018- NeoTIL-2019	Lymphodepletion: Cyclophosphamide +Fludarabine Radtioherapy NeoTILs and IL-2	Patients with advanced (not radically treatable), recurrent or metastatic solid tumors of any histology with the exception of primary central nervous system tumors NSCLC: SQ and non SQ	Patient who progressed or been intolerant to at least one standard therapy regimen in the advanced or metastatic setting	 NSCLC: SQ and non SQ Age ≥ 18 to ≤ 70 years. If ≥ 70yo, discussion and decision with PI Measurable disease as per RECIST 1.1 in addition to resectable lesions ECOG 0-2 with life expectancy ≥ 3months
THOR	BMS CA224-048 Phase I/II	Nivolumab + Relatlimab + Ipilimumab	Stage IIIB, IV or recurrent NSCLC (squamous or non squamous)	Prior adjuvant or neoadj. chemo permitted (at least 6 months prior enrolment) + IO naive	 No prior systemic anticancer therapy IO naive, except for participants with targetable mutations (ALK, EGFR, ROS1, BRAF) who must have had prior treatment with approved targeted therapy Prior definitive chemoradiation for locally advanced disease is also permitted as long as the last administration of chemotherapy or radiotherapy (which ever was given last) occurred at least 6 months prior to enrollment. Patient without archived tissue less than 3 months old must undergoo a MANDATORY pretreatment biopsy At least 1 measurable lesion as per RECIST1.1 ECOG 1; Life expectancy ≥ 12 weeks at time of infomed consent; LVEF ≥ 50 % No history of interstitial lung disease/pneumonitis; No known or suspected CNS metastases; No active, known or suspected autoimmune disease, no uncontrolled or significant cardiovascular disease; No history of of life threatening toxicity related to prior immunotherapy; No history of encephalitis, meningitis; No TnT or TnI > 2 x ULN; no blood transfusion within 4 weeks of C1D1



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gynécologie/sénologie

CONTACTS

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ndication	Study name	Treatment	Stage & histological type	Line	Other key eligibility criteria
SENO	CHUV-DO-0009- CyberimmunoBreast- 2017	pre-operative SBRT in early stage TNBC +/- CMP-001	Histologically confirmed triple negative breast cancer of early stage (cT1-2 cN0-1 cM0) according to immunohistochemistry/FISH and current ASCO guidelines. TNBC subtype is defined as: ER <10% and PR <10% and HER2 negative Women with bilateral breast TNBC can be acceptable if both sides are TNBC (treatment is allowed to be administered to one breast only)	Patients who have a diagnosis of early TNBC, for whom a surgical treatment is indicated (Breast Conservative Surgery or Mastectomy), and who do not require neoadjuvant therapy,	 ECOG 0 to 1 A planned breast cancer surgery No planned neoadjuvant chemotherapy/endocrine therapy or other anticancer biologic therapy. Presence of measurable disease in the breast, defined as a lesion that can be accurately measured in at leas one dimension with conventional techniques (MRI, or ultrasound). Primary tumor accessible to injection and biopsy Prohibited therapies: Any prior ipsilateral breast irradiation
Any solid tumor	CHUV-DO-0018- NeoTIL-2019	Lymphodepletion: Cyclophosphamide +Fludarabine Radtioherapy NeoTILs and IL-2	Patients with advanced (not radically treatable), recurrent or metastatic solid tumors of any histology with the exception of primary central nervous system tumors For Gyn: HPV induced cancers For Sen: Any BC	Patient who progressed or been intolerant to at least one standard therapy regimen in the advanced or metastatic setting	 For Gyn: HPV induced cancer Age ≥ 18 to ≤ 70 years. If ≥ 70yo, discussion and decision with PI Measurable disease as per RECIST 1.1 in addition to resectable lesions ECOG 0-2 with life expectancy ≥ 3months
SENO	Amgen TVEC intra-tumoral 20140318 Phase I	TVEC+ pembrolizumab	- TNBC - Hormone receptor positive BC	At least 1 prior systemic treatment line	 Measurable tumor lesions that are suitable for injection (≥ 1 cm) Hormone Receptor positive BC: Histologically and/or cytologically confirmed diagnosis of ER positive and/or PrR positive TNBC: Histologically and/or cytologically confirmed diagnosis of ER negative, PrR negative, human epidermal growth factor receptor 2 (HER2)-Neu negative Hormone receptor positive BC: No prior treatment with a checkpoint inhibitor. Progression on or following at least 1 prior standard of care systemic anti-cancer therapy Subjects with previously treated cerebral metastases may be enrolled, provided that all lesions have been adequately treated Liver tumors must not be estimated to invade approximately more than one-third of the liver; Liver tumor-directed therapy, hepatic surgery, antibody-based therapy, or immunotherapy must not have been performed < 28 days, chemotherapy < 21 days, and targeted small molecule therapy or hormonal therapy < 14 days prior to enrollment; ≤ grade 1 toxic effects of prior therapy and/or complications from prior intervention before starting therapy No prior therapy with tumor vaccine, TVEC or oncolytic virus Life expectancy ≥ 5 months



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Unil_ UNIL Université de Lausanne	CUV
UNIL Université de Lausanne	

ndication	Study name	Treatment	Stage & histological type	Line	Other key eligibility criteria
GI Pancreas	CHUV-Do PEP-DC	Adjuvant SOC chemotharap (capecitabine, gemcitabien)+ Vaccin PEP_DC vaccin Nivolumab maintenance	T1-T4 N0-2	No distant metastase	 Appropriate amount of tumoral tissue was collected from the cytoreductive surgery and allowed the identification of top 10 personalized peptides (PEP) for preparation of PEP-DC vaccine No measurable tumor lesion according to radiologic criteria -Recovery from any toxic effects of prior neo-adjuvant therapy to ≤ Grade 1 per the National Cancer Institute Common Terminology Criteria for Adverse Events (NCI CTCAE v4.03) except for toxicities described below, as long as they do not put at risk the patient's condition and do not require systemic immunosuppressive steroids at any dose, including but not limited to: Fatigue, Alopecia, Skin disorders, Stable neuropathy, Endocrinopathies requiring replacement treatment
GI Colorectal	BMS CA022-001 Phase I	Part IB (Nivolumab 480mg + BMS 986218 NFIPI)	Advanced solid tumor	Part 1B: Progressed or relapse after at least 2 standard systemic with proven survival benefit according to their tumor type in advanced or metastatic disease	 ECOG PS: 0-1 Progressed after prior immunotherapy with anti-PD-1 / anti-PD-L1 either by itself or in combination with other systemic therapy agents Patients with Toxicity (except for alopecia) related to prior anti-cancer therapy and/or surgery, unless the toxicity is either resolved, returned to baseline or Grade 1, or deemed irreversible. No Prior participation in an anti-CTLA-4-NF clinical study or therapy Participants with primary CNS malignancies, or tumors with CNS metastases as the only site of disease, will be excluded

GI	
Liver	

Amgen TVEC intra-tumoral 20140318 Phase I

TVEC ou

 Hepatocellular carcinoma (HCC) with
 HCC: any; TVEC+ pembrolizumab known disease progression

- With active hepatitis B or C (cohort
- (cohort 6b)

•CRC

- Without active hepatitis B or C
- Measurable liver tumors that are suitable for injection (≥ 1 cm)
- Liver tumors must not be estimated to invade approximately more than one-third of the liver:
- Liver tumor-directed therapy, hepatic surgery, antibody-based therapy, or immunotherapy must not have been performed < 28 days, chemotherapy < 21 days, and targeted small molecule therapy or hormonal therapy < 14 days prior to enrollment;
- ≤ grade 1 toxic effects of prior therapy and/or complications from prior intervention before starting therapy
- •CRC: at least 1 prior systemic treatment No prior therapy with tumor vaccine, TVEC or oncolytic virus
 - Life expectancy ≥ 5 months
 - HCC: no central nervous system (CNS) metastasis
 - CRC: Subjects with previously treated cerebral metastases may be enrolled, provided that all lesions have been adequately treated
 - •CRC: Progression on or following at least 1 prior standard of care systemic anti-cancer therapy
 - Cohort 6b: Subjects must have a diagnosis of hepatitis B and/or C (HBV and HCV). Subjects with HCV infection must have completed treatment for their hepatitis C at least 4 weeks prior to study enrollment, and HCV viral load must be undetectable.

Subjects with controlled HBV will be eligible as long as they meet the following criteria:

- Antiviral therapy for HBV must be given for at least 4 weeks and HBV viral load must be < 100 IU/mL prior to enrollment. Participants on active HBV therapy with viral loads < 100 IU/mL should stay on the same therapy throughout study treatment.
- Subjects who are positive for anti-hepatitis B core antibody HBc, negative for hepatitis B surface antigen (HBsAg), and negative or positive for anti-hepatitis B surface antibody (HBs), and who have an HBV viral load < 100 IU/mL, do not require HBV anti-viral prophylaxis.



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Indication	Study name	Treatment	Stage & histological type	Line	Other key eligibility criteria
Any solid tumor	CHUV-DO-0018- NeoTIL-2019	Lymphodepletion: Cyclophosphamide +Fludarabine Radtioherapy NeoTILs and IL-2	Patients with advanced (not radically treatable), recurrent or metastatic solid tumors of any histology with the exception of primary central nervous system tumors	Patient who progressed or been intolerant to at least one standard therapy regimen in the advanced or metastatic setting	 Age ≥ 18 to ≤ 70 years. If ≥ 70yo, discussion and decision with PI Measurable disease as per RECIST 1.1 in addition to resectable lesions ECOG 0-2 with life expectancy ≥ 3months
GI	BMS CA027-002 Phase I/lia	BMS-986253 (any IL8 level) + Nivolumab + Ipilimumab	Histologically or radiologically confirmed HCC (radiological diagnosis must be confirmed histologically at screening) Histologically confirmed, advanced, unresectable or metastatic) MSS CRC	All participants must have received, and then progressed, relapsed, or been intolerant to at least 1 standard treatment regimen in the advanced or metastatic setting according to tumor type	 Advanced solid tumor with at least 1 lesion accessible for biopsy in addition to the target lesion ECOG 0-1 For MSS CRC: Microsatellite instability must be documented Participants must have received and progressed on, or intolerant to fluoropyrimidine, oxaliplatin and irinotecan For HCC:
GI	SEAGEN SGNB6A-001 Phase I	SGNB6A-001	Locally advanced or metastatic esophageal carcinoma	Subjects must have received prior platinum-based chemotherapy. If eligible by biomarker status and consistent with standard-of-care, must have received a prior PD-1/PD-L1 inhibitor.	 Must have measurable disease ECOG 0-1 and life expectancy > 3months Mandatory biopsy at screening NO neuropathy ≥ Grade 2 per NCI CTCAE v5.0 NO Uncontrolled diabetes mellitus



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mélanome

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Indication	Study name	Treatment	Stage & histological type	Line	Other key eligibility criteria
MEL	BMS CA224-048 Phase I/II	Nivolumab Q4W + Relatlimab Q4W + IDO1 inhibitor oral 1x/j	Untreated, unresectable stage III or IV melanoma	1st line	 Both BRAF V600 wild-type and -mutant melanoma participants are allowed and mutation status must be documented. Prior neoadjuvant and adjuvant treatments (including cytokines, interferon, and anti-CTLA-4 and anti-PD-1/PD-L1) are allowed, if completed at least 6 months prior to enrollment and all related AEs have either returned to baseline or stabilized. Cannot have had prior exposure to any IO therapies other than cytokines, interferon, anti-CTLA-4 and/or anti-PD-1/PD-L1 antibody therapy. Uveal melanoma participants are not allowed Patient without archived tissue less than 3 months old must undergoo a MANDATORY pretreatment biopsy At least 1 measurable lesion as per RECIST1.1 ECOG 1; Life expectancy ≥ 12 weeks at time of infomed consent; LVEF ≥ 50 % No history of interstitial lung disease/pneumonitis; No known or suspected CNS metastases; No active, known or suspected autoimmune disease, no uncontrolled or significant cardiovascular disease; No history of ol life threatening toxicity related to prior immunotherapy; No history of encephalitis, meningitis; No TnT or TnI > 2 x ULN; no blood transfusion within 4 weeks of C1D1
MEL	BMS CA224-020 Phase I/lia	Anti Lag-3 + Nivolumab	Melanoma	ONLY IO NAÏVE MELANOMA COHORT OPEN Cohort 2: participants who have not received prior systemic anticancer therapy for unresectable or metastatic melanoma (confirmed stage III or stage IV)	 Histologic or cytologic confirmation of an incurable solid malignancy that is advanced (metastatic and/or unresectable) BRAF status must be known Must have measurable disease ECOG 0-1 and life expectancy > 3months Mandatory biopsy at screening Troponin T or I must be ≤ 2 x ULN Prior neodajuvant/adjuvant therapies allowed with certain condition Uveal melanoma NOT eligible
MEL	TVEC intra-tumoral 20140318 Phase I	TVEC+ pembrolizumab TVEC injections into: Liver, lymph nodes, cutaneous and sub- cutaneous lesions	-Basal Cell Carcinoma (BCC) - Cutaneous Squamous Cell Carcinoma (CSCC)	BCC: at least 1 prior systemic treatment line CSCC: any	 Measurable tumor lesions that are suitable for injection (≥ 1 cm) BCC: No prior treatment with a checkpoint inhibitor. BCC: Progression on or following at least 1 prior standard of care systemic anti-cancer therapy Subjects with previously treated cerebral metastases may be enrolled, provided that all lesions have been adequately treated Liver tumors must not be estimated to invade approximately more than one-third of the liver; Liver tumor-directed therapy, hepatic surgery, antibody-based therapy, or immunotherapy must not have been performed < 28 days, chemotherapy < 21 days, and targeted small molecule therapy or hormonal therapy < 14 days prior to enrollment; ≤ grade 1 toxic effects of prior therapy and/or complications from prior intervention before starting therapy No prior therapy with tumor vaccine, TVEC or oncolytic virus Life expectancy ≥ 5 months

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mélanome

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Indication	Study name	Treatment	Stage & histological type	Line	Other key eligibility criteria
MEL	CHUV-DO-0018- NeoTIL-2019	Lymphodepletion: Cyclophosphamide +Fludarabine Radtioherapy NeoTILs and IL-2	Patients with advanced (not radically treatable), recurrent or metastatic solid tumors of any histology with the exception of primary central nervous system tumors	Patient who progressed or been intolerant to at least one standard therapy regimen in the advanced or metastatic setting	 For Melanoma: Includes cutaneous Age ≥ 18 to ≤ 70 years. If ≥ 70yo, discussion and decision with PI Measurable disease as per RECIST 1.1 in addition to resectable lesions ECOG 0-2 with life expectancy ≥ 3months
			For Melanoma: Includes cutaneous		
MEL	BMS CA027-002 Phase I/lia	Melanoma (Part 1B) BMS-986253 (IL8 > 10pg) + Nivolumab Melanoma (Part 1C): BMS-986253 (any IL8 level) + Nivolumab + Ipilimumab	Histologically confirmed, unresectable Stage III or Stage IV melanoma. Ocular or uveal melanoma are ineligible.	treatment regimen in the advanced or metastatic setting according to tumor	 Advanced solid tumor with at least 1 lesion accessible for biopsy in addition to the target lesion ECOG 0-1 Participants in Part 1: Must have documented progressive or recurrent disease on or within 3 months of discontinuation of anti-PD-(L)1 therapy (administered as monotherapy or as part of a combination) as per RECIST 1.1 criteria. Prior PD-(L)1-based therapy must be the most recent treatment. BRAF (V600) mutation status must be known
MEL	BMS CA022-001 Phase I	- Bras 1 Ipilimumab monotherapy - Bras 2-3 et 4 monotherapy BMS 986218 (7, 20 ou 70mg	Advanced	received standard therapies with proven survival benefit including prior immunotherapy with an anti-PD-1 or	 -ECOG PS: 0-1 -progressed after prior immunotherapy with anti-PD-1 / anti-PD-L1 either by itself or in combination with other systemic therapy agents Patients with Toxicity (except for alopecia) related to prior anti-cancer therapy and/or surgery, unless the toxicity is either resolved, returned to baseline or Grade 1, or deemed irreversible. No Prior participation in an anti-CTLA-4-NF clinical study or therapy Participants with primary CNS malignancies, or tumors with CNS metastases as the only site of disease, will be excluded Participants with advanced stage cutaneous melanoma who have received standard therapies with proven survival benefit including prior immunotherapy with an anti-PD-1 or anti-PD-L1 containing regimen and must have progressive or recurrent disease after prior PD-1/PD-L1 directed therapy. No more than 70% of the randomized participants should have had progression of disease within a period of 6 months of start of therapy with anti-PD-1/PD-L1 agent



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urologie

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Indication	Study name	Treatment	Stage & histological type	Line	Other key eligibility criteria
URO	BMS CA022-001 Phase I	Part IB (Nivolumab 480mg + BMS 986218)	advanced	Part 1B: Progressed or relapse after at least 2 standard systemic with proven survival benefit according to their tumor type in advanced or metastatic disease Part 2B: NSCLC prior anti PD-1 /anti PD-L1	 ECOG PS: 0-1 if anti-PD-1 therapy is approved in a given indication, participants are eligible to receive this treatment as part of the combination regimen in this study prior to having completed 2 prior systemic therapy regimens after discussion and agreement with the Medical Monitor (or designee) Toxicity (except for alopecia) related to prior anti-cancer therapy and/or surgery, unless the toxicity is either resolved, returned to baseline or Grade 1, or deemed irreversible. No Prior participation in an anti-CTLA-4-NF clinical study or therapy Participants with primary CNS malignancies, or tumors with CNS metastases as the only site of disease, will be excluded
URO	BMS CA027-002 Phase I/IIa	UCC + RCC (Part 1B): BMS-986253 (IL8 > 10pg) + Nivolumab UCC (Part 1C): BMS-986253 (any IL8 level) + Nivolumab + Ipilimumab	Histologically confirmed, advanced (ie, unresectable or metastatic) squamous cell carcinoma of the Urothelium involving the bladder, uretra, ureter or renal pelvis Renal cell carcinoma with a clear cell component	All participants must have received, and then progressed, relapsed, or been intolerant to at least 1 standard treatment regimen in the advanced or metastatic setting according to tumor type	 Advanced solid tumor with at least 1 lesion accessible for biopsy in addition to the target lesion ECOG 0-1 Must have documented progressive or recurrent disease on or within 3 months of discontinuation of anti-PD-(L)1 therapy (administered as monotherapy or as part of a combination) as per RECIST 1.1 criteria. Prior PD-(L)1-based therapy must be the most recent treatment.
Any solid tumor	CHUV-DO-0018- NeoTIL-2019	Lymphodepletion: Cyclophosphamide +Fludarabine Radtioherapy NeoTILs and IL-2	Patients with advanced (not radically treatable), recurrent or metastatic solid tumors of any histology with the exception of primary central nervous system tumors Uro: RCC only	Patient who progressed or been intolerant to at least one standard therapy regimen in the advanced or metastatic setting	 Age ≥ 18 to ≤ 70 years. If ≥ 70yo, discussion and decision with PI Measurable disease as per RECIST 1.1 in addition to resectable lesions ECOG 0-2 with life expectancy ≥ 3months



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ORL	BMS CA224-048 Phase I/II	Nivo 480mg Q4W Relatlimab 160mg Q4W IDO1 inhibitor oral 1x/j	Histology restricted to SCCHN from any of the following primary sites only: oral cavity, oropharynx, hypopharynx, and larynx.	Must have metastatic or recurrent SCCHN not amenable to therapy with curative intent (surgery or radiation therapy with or without chemotherapy).	 IO naive Patient without archived tissue less than 3 mor biopsy At least 1 measurable lesion as per RECIST1.1 Eligible regardless of HPV status (HPV status mr ECOG 1; Life expectancy ≥ 12 weeks at time of No GGPD deficiency; No hypersensitivity or idic 	
				Participants who have progressed	serotonin syndrome or cyt b5 reductase deficie	

- onths old must undergoo a MANDATORY pretreatment
- must be documented)
- of infomed consent; LVEF ≥ 50 %
- diosyncratic reaction to methylene blue; No history of serotonin syndrome or cyt b5 reductase deficiency or disease that put at risk of methemoglobinemia; No known or suspected CNS metastases; No active, known or suspected autoimmune disease, no uncontrolled or significant cardiovascular disease; No history of life threatening toxicity related to prior immunotherapy; No history of encephalitis, meningitis; No TnT or TnI > 2 x ULN; no blood transfusion within 4 weeks of C1D1

ORL	BMS CA027-002 Phase I/IIa	BMS-986253 (anti-IL- 8) + Nivolumab	Histologically confirmed, advanced (ie, unresectable or metastatic) squamous cell carcinoma of the Oral Cavity, Pharynx, Larynx.	All participants must have received, and then progressed, relapsed, or been intolerant to at least 1 standard treatment regimen in the advanced or metastatic setting according to tumor type

- Advanced solid tumor with at least 1 lesion accessible for biopsy in addition to the target lesion ECOG 0-1
- -Participants must have documented progressive or recurrent disease on or within 3 months of discontinuation of anti-PD-(L)1 therapy (administered as monotherapy or as part of a combination) as per RECIST 1.1 criteria.
- Prior PD-(L)1-based therapy must be the most recent treatment.
- For SCC of the oropharynx, HPV status must be documented. Both HPV-positive
- or HPV-negative participants are permitted in this cohort.

SAKK 11/16: MVX-**ORL** ONCO-1 in advanced HNSCC

MVX-ONCO-1: Patients with advanced HNSCC (stage composed of III/IV) in recurrent or metastatic stage irradiated with disease progression autologous tumor cells and an

One line of prior anticancer therapy for • recurrent or metastatic disease. Patients with locally advanced disease experiencing local relapse within 6 months of last dose of curative intended, platinum-based chemoradiation with or without prior surgery can also be included

within 6 months of platinum-based

therapy used as part of concurrent

adjuvant therapy) are also eligible.

chemoradiation (definitive or

- [Incl]Primary tumor and/or metastasis amenable for partial/total surgery or tap and subsequent cell harvest >26x106 cells
- [Incl]WHO performance status 0-2
- [Exc]Known or suspected CNS metastases or active leptomeningeal disease
- [Exc]Any chemotherapy treatment in the 4 preceding weeks of the pre-registration
- [Exc]History of hematologic or primary solid tumor malignancy, unless in remission for at least 3 years from registration with the exception of T1-2 prostate cancer Gleason score <6, adequately treated cervical carcinoma in situ or localized non-melanoma skin cancer

ORL

SEAGEN SGNB6A-001 Phase I

SGNB6A-001

immune-modulator

Locally advanced or metastatic head and neck cancers

Subjects must have received platinumbased therapy and a PD-1/PD-L1 inhibitor, if eligible by biomarker status • and local standard of care. These agents may have been administered either as single agents or in combination

- Must have measurable disease
- ECOG 0-1 and life expectancy > 3months
- Mandatory biopsy at screening
- NO neuropathy ≥ Grade 2 per NCI CTCAE v5.0
- NO Uncontrolled diabetes mellitus



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sarcomes

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Indication	Study name	Treatment	Stage & histological type	Line	Other key eligibility criteria
SARC	CHUV-DO-0018- NeoTil-2019	Lymphodepletion: Cyclophosphamide +Fludarabine Radtioherapy NeoTILs and IL-2	Patients with advanced (not radically treatable), recurrent or metastatic solid tumors of any histology with the exception of primary central nervous system tumors	Patient who progressed or been intolerant to at least one standard therapy regimen in the advanced or metastatic setting	 Age ≥ 18 to ≤ 70 years. If ≥ 70yo, discussion and decision with PI Measurable disease as per RECIST 1.1 in addition to resectable lesions ECOG 0-2 with life expectancy ≥ 3months

